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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA, INC. and POZEN INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD.,

Defendants.

Civil Action No. 3:15-cv-03324-MLC-DEA

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Horizon Pharma, Inc. and Pozen Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Horizon Pharma, Inc. ("Horizon") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015.

2. Plaintiff Pozen Inc. ("Pozen") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

3. On information and belief, Defendant Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") is a corporation operating and existing under the laws of the State of New Jersey, with its principal place of business at 107 College Road East, Princeton, NJ 08540.

4. On information and belief, Defendant Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India 500 034.

5. On information and belief, Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd.

BACKGROUND

The NDA

6. Horizon is the holder of New Drug Application ("NDA") No. 022511 for VIMOVO® (naproxen and esomeprazole magnesium) Delayed-Release Tablets, in 375 mg

(naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) dosage forms.

7. VIMOVO® Delayed-Release Tablets are prescription drugs approved for use to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Naproxen and esomeprazole magnesium are the active ingredients in VIMOVO® Delayed-Release Tablets.

The Patents-in-Suit

8. United States Patent No. 8,852,636 ("the '636 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs" was duly and legally issued by the United States Patent and Trademark Office on October 7, 2014. The claims of the '636 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen (claims 1–4, 7–10, 13–18) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 5–6, 11–12). A true and correct copy of the '636 patent is attached as Exhibit A.

9. Pozen owns the '636 patent by assignment. Horizon is Pozen's exclusive licensee under the '636 patent. The '636 patent will expire on May 31, 2022.

10. The '636 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

11. United States Patent No. 8,858,996 ("the '996 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 14, 2014. The claims of the '996 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and

naproxen (claims 1–9, 12–15) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 10–11, 16–19). A true and correct copy of the '996 patent is attached as Exhibit B.

12. Pozen owns the '996 patent by assignment. Horizon is Pozen's exclusive licensee under the '996 patent. The '996 patent will expire on May 31, 2022.

13. The '996 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

14. United States Patent No. 8,865,190 ("the '190 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 21, 2014. The claims of the '190 patent are directed to a process for preparing pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen. A true and correct copy of the '190 patent is attached as Exhibit C.

15. Pozen owns the '190 patent by assignment. Horizon is Pozen's exclusive licensee under the '190 patent. The '190 patent will expire on May 31, 2022.

Related Patents

16. United States Patent No. 6,926,907 ("the '907 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on August 9, 2005. The claims of the '907 patent are directed to pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and an NSAID (claims 1–21, and 53–55) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 22–52).

17. Pozen owns the '907 patent by assignment. Horizon is Pozen's exclusive licensee under the '907 patent. The '907 patent will expire on February 28, 2023.

18. The '907 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® drug product.

19. United States Patent No. 8,557,285 ("the '285 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 15, 2013. The claims of the '285 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen.

20. Pozen owns the '285 patent by assignment. Horizon is Pozen's exclusive licensee under the '285 patent. The '285 patent will expire on May 31, 2022.

21. The '285 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® drug product.

The ANDAs

22. On information and belief, Defendants filed ANDA No. 202461 ("ANDA I") with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and sale in the United States of naproxen and esomeprazole magnesium delayed-release tablets containing 375 mg or 500 mg of naproxen and 20.71 mg esomeprazole magnesium ("ANDA I Product"), which are generic versions of Plaintiffs' VIMOVO® Delayed-Release Tablets in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) strengths, respectively.

23. By letter dated March 11, 2011 (the "ANDA I Notice Letter"), Defendants notified AstraZeneca AB (Horizon's predecessor-in-interest as holder of NDA No. 022511 and

as exclusive licensee for the '907 patent and the '285 patent) and Pozen that Defendants had filed ANDA No. 202461 seeking approval to market ANDA I Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding the '907 patent.

24. On information and belief, ANDA I received tentative approval on August 12, 2013 and final approval on September 27, 2013.

25. On information and belief, Defendants filed ANDA No. 204206 ("ANDA II") with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and sale in the United States of naproxen and esomeprazole magnesium delayed-release tablets containing 375 mg or 500 mg of naproxen and 20.71 mg esomeprazole magnesium ("ANDA II Product"), which are generic versions of Plaintiffs' VIMOVO® Delayed-Release Tablets in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) strengths, respectively.

26. By letter dated November 20, 2012 (the "ANDA II Notice Letter"), Defendants notified AstraZeneca AB and Pozen that Defendants had filed ANDA No. 204206 seeking approval to market Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding certain patents including the '907 patent.

27. On January 23, 2015, Plaintiffs requested that Defendants provide Paragraph IV certifications for ANDA No. 204206 with respect to *inter alia* the patents in suit.

28. By letter dated April 20, 2015, Defendants notified Horizon and Pozen that Defendants had filed ANDA No. 204206 seeking approval to market Defendants' ANDA

Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding the '285, '636, and '996 patents.

29. Plaintiffs have diligently sought access to confidential information from Defendants to evaluate Defendants' infringement of the '190 patent. To date, Defendants have not responded to Plaintiffs' requests. Accordingly, resort to the civil court process, with the protections and procedures of the discovery process, is necessary to ensure access to Defendants' confidential information about the DRL I product and the DRL II product and how they are made. This information is needed to confirm Plaintiffs' belief that the DRL I product and the DRL II product infringe the '190 patent.

JURISDICTION AND VENUE

30. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

31. On information and belief, Defendants have been and are engaging in activities directed toward infringement of the '636, '996, and '190 patents (collectively, the "patents-in-suit") by, *inter alia*, submitting to the FDA ANDA Nos. 202461 and 204206, receiving final approval to market ANDA I Product, and continuing to seek approval for ANDA II Product.

32. Defendants' ANDA I Notice Letter and ANDA II Notice Letter states Defendants' intention to seek FDA approval to market a generic version of the VIMOVO® product before the related '907 patent expires on February 28, 2023.

33. There is now an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the '636, '996, and '190 patents.

34. On information and belief, Dr. Reddy's Inc. is a corporation organized and existing under the laws of the State of New Jersey. By virtue of its incorporation in New Jersey, this Court has personal jurisdiction over Dr. Reddy's Inc.

35. On information and belief, Defendants are in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing pharmaceutical products.

36. On information and belief, Dr. Reddy's Ltd., either directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

37. On information and belief, Dr. Reddy's Inc., with the assistance and/or at the direction of Dr. Reddy's Ltd., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

38. On information and belief, Defendants acted in concert to develop ANDA I Product and ANDA II Product and to seek approval from the FDA to sell ANDA I Product and ANDA II Product throughout the United States, including within this judicial district.

39. On information and belief, both Dr. Reddy's Ltd. and Dr. Reddy's Inc. participated in the preparation and/or filing of ANDA Nos. 202461 and 204206.

40. On information and belief and as stated in the ANDA I Notice Letter and the ANDA II Notice Letter, the FDA received ANDA Nos. 202461 and 204206 from Dr. Reddy's Ltd. and Dr. Reddy's Inc.

41. In their ANDA I Notice Letter and in their ANDA II Notice Letter, Defendants stated that the name and address of their agent in the United States authorized to accept service of process for Defendants for purposes of an infringement action based upon the ANDA I Notice Letter or the ANDA II Notice Letter is Lee Banks, Dr. Reddy's Laboratories Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807.

42. By naming Lee Banks, Dr. Reddy's Laboratories Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807 as their agents in the ANDA I Notice Letter and the ANDA II Notice Letter, Defendants have consented to jurisdiction in the State of New Jersey for this action.

43. On information and belief, by virtue of, *inter alia*, Dr. Reddy's Ltd.'s relationship with Dr. Reddy's Inc. in connection with the preparation and/or filing of ANDA Nos. 202461 and 204206; Dr. Reddy's Ltd.'s designation of Lee Banks, Dr. Reddy's Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807 as its agent for service of process; and the sales-related activities of Defendants in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, this Court has personal jurisdiction over Dr. Reddy's Ltd.

44. On information and belief, Defendants have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g.*, *Wyeth LLC v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civ. Action No. 3:10-cv-04551-FLW-DEA (D.N.J.); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civ. Action No. 2:09-cv-04638-GEB-MCA (D.N.J.); *Sepracor, Inc. v. Teva Pharm. USA, Inc., et al.*, Civ. Action No. 2:09-cv-01302-DMC-MF (D.N.J.); *Hoffman-La Roche Inc. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civ. Action No. 2:08-cv-04055-SRC-MAS (D.N.J.); *AstraZeneca AB et*

al. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc., Civil Action No. 3:08-cv-00328-JAP-TJB (D.N.J.); and *AstraZeneca AB et al. v. Dr. Reddy's Labs, Inc. and Dr. Reddy's Labs., Ltd.*, Civil Action Nos. 3:11-cv-02317-JAP-DEA (D.N.J.) and 3:13-cv-00091-JAP-DEA (D.N.J.).

45. On information and belief, both Defendants Dr. Reddy's Ltd. and Dr. Reddy's Inc. have admitted that each is subject to personal jurisdiction in this district. *See, e.g.*, *AstraZeneca UK Ltd. and AstraZeneca Pharms. LP v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, 3:08-cv-03237-MLC-TJB (D.N.J.), Answer to Complaint, ¶ 8 (July 11, 2008); *AstraZeneca AB et al. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, 3:11-cv-02317-JAP-DEA (D.N.J.), Answer to Second Amended Complaint, ¶ 29.

46. On information and belief, Defendants have availed themselves of the jurisdiction of this Court by initiating litigation in this district. *See, e.g., Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc. v. Eli Lilly & Co.*, Civ. Action No. 3:09-0192-GEB-LHG (D.N.J.); and *Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc. v. AstraZeneca AB et al.*, Civil Action No. 3:08-cv-02496-JAP-TJB (D.N.J.).

47. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA Nos. 202461 and 204206, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

48. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

COUNT I
(INFRINGEMENT OF THE '636 PATENT UNDER 35 U.S.C. § 271(e)(2))

49. Plaintiffs incorporate by reference paragraphs 1–488 of this Complaint as if fully set forth herein.

50. The ’636 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

51. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the ’636 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA’s Orange Book.

52. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV”) requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the ’636 patent, “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .” The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include “[a] detailed statement of the factual and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.”

53. On information and belief, Defendants were aware of the statutory provisions and regulations referred to in paragraph 48 above when they served the ANDA I Notice Letter and ANDA II Notice Letter regarding certain patents including the ’907 patent.

54. On information and belief, Defendants have previously filed patent certifications in association with their ANDA Nos. 202461 and 204206 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The '636 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204206 before the '636 patent expires.

55. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), Defendants should file a patent certification in their pending ANDA No. 204206 with respect to the '636 patent and must make a Paragraph IV certification with respect to the '636 patent if Defendants continue to seek FDA final approval of their ANDA No. 204206 before the '636 patent expires.

56. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA II Product infringes the '636 patent.

57. Defendants have infringed, either literally or under the doctrine of equivalents, the '636 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 204206 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug claimed in the '636 patent before the expiration of the '636 patent.

58. On information and belief, Defendants' ANDA II Product contains the pharmaceutical composition patented in the '636 patent, is a material for use in practicing the methods patented in the '636 patent, constitutes a material part of the inventions of the '636 patent, is especially made or especially adapted for use in an infringement of the '636 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA II Product is so made or so

adapted. On information and belief, Defendants are aware that the ANDA II Product, if approved, will be used in contravention of Plaintiffs' rights under the '636 patent.

59. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '636 patent under 35 U.S.C. § 271(e)(2).

60. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT II
(DECLARATORY JUDGMENT AS TO THE '636 PATENT)

61. Plaintiffs incorporate by reference paragraphs 1–60 of this Complaint as if fully set forth herein.

62. The '636 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

63. On information and belief, Defendants' ANDA I Product and ANDA II Product contain the pharmaceutical composition patented in the '636 patent, are materials for use in practicing the methods patented in the '636 patent, constitute a material part of the inventions of the '636 patent, are especially made or especially adapted for use in an infringement of the '636 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA I Product and the ANDA II Product are so made or so adapted.

64. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA I Product or

ANDA II Product before the expiration of the '636 patent constitutes infringement of the '636 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

65. On information and belief, Defendants have previously filed patent certifications in association with their ANDA Nos. 202461 and 204206 seeking, *inter alia*, FDA final approval to market the ANDA I Product and the ANDA II Product before February 28, 2023.

66. The ANDA I Notice Letter and the ANDA II Notice Letter show Defendants' intent to market the ANDA I Product and the ANDA II Product before the '636 patent expires on May 31, 2022.

67. On information and belief, Defendants received FDA final approval to market the ANDA I Product on September 27, 2013. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA I Product before the expiration of the '636 patent will infringe the '636 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

68. On information and belief, Defendants continue to seek FDA final approval for ANDA Product II. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA II Product, if approved, will infringe the '636 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

69. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States their ANDA I Product and ANDA II Product before the '636 patent expires.

70. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA I Product before the '636 patent expires. On information and belief, Defendants may launch their ANDA I Product at any time.

71. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA II Product after receiving FDA final approval of ANDA No. 204206 and before the '636 patent expires.

72. Defendants maintain, on information and belief, and Plaintiffs deny that the '636 patent is invalid or unenforceable and that Defendants' ANDA I Product and ANDA II Product do not or will not infringe the '636 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '636 patent by Defendants' ANDA I Product and ANDA II Product.

73. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

74. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of ANDA Product I or ANDA Product II will infringe one or more claims of the '636 patent.

COUNT III
(INFRINGEMENT OF THE '996 PATENT UNDER 35 U.S.C. § 271(e)(2))

75. Plaintiffs incorporate by reference paragraphs 1–74 of this Complaint as if fully set forth herein.

76. The ’996 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

77. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the ’996 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA’s Orange Book.

78. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV”) requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the ’996 patent, “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .” The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include “[a] detailed statement of the factual and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.”

79. On information and belief, Defendants were aware of the statutory provisions and regulations referred to in paragraph 74 above when they served the ANDA I Notice Letter and ANDA II Notice Letter regarding certain patents including the ’907 patent.

80. On information and belief, Defendants have previously filed patent certifications in association with their ANDA Nos. 202461 and 204206 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The '996 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204206 before the '996 patent expires.

81. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), Defendants should file a patent certification in their pending ANDA No. 204206 with respect to the '996 patent and must make a Paragraph IV certification with respect to the '996 patent if Defendants continue to seek FDA final approval of their ANDA No. 204206 before the '996 patent expires.

82. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA II Product infringes the '996 patent.

83. Defendants have infringed, either literally or under the doctrine of equivalents, the '996 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 204206 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug claimed in the '996 patent before the expiration of the '996 patent.

84. On information and belief, Defendants' ANDA II Product contains the pharmaceutical composition patented in the '996 patent, is a material for use in practicing the methods patented in the '996 patent, constitutes a material part of the inventions of the '996 patent, is especially made or especially adapted for use in an infringement of the '996 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA II Product is so made or so

adapted. On information and belief, Defendants are aware that the ANDA II Product, if approved, will be used in contravention of Plaintiffs' rights under the '996 patent.

85. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '996 patent under 35 U.S.C. § 271(e)(2).

86. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV
(DECLARATORY JUDGMENT AS TO THE '996 PATENT)

87. Plaintiffs incorporate by reference paragraphs 1–86 of this Complaint as if fully set forth herein.

88. The '996 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

89. On information and belief, Defendants' ANDA I Product and ANDA II Product are made using the process patented in the '996 patent, constitute a material part of the inventions of the '996 patent, are especially made or especially adapted for use in an infringement of the '996 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA I Product and the ANDA II Product are so made or so adapted.

90. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA I Product or ANDA II Product before the expiration of the '996 patent constitutes infringement of the '996 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

91. On information and belief, Defendants have previously filed patent certifications in association with their ANDA Nos. 202461 and 204206 seeking, *inter alia*, FDA final approval to market the ANDA I Product and the ANDA II Product before February 28, 2023.

92. The ANDA I Notice Letter and the ANDA II Notice Letter show Defendants' intent to market the ANDA I Product and the ANDA II Product before the '996 patent expires on May 31, 2022.

93. On information and belief, Defendants received FDA final approval to market the ANDA I Product on September 27, 2013. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA I Product before the expiration of the '996 patent will infringe the '996 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

94. On information and belief, Defendants continue to seek FDA final approval for ANDA Product II. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA II Product, if approved, will infringe the '996 patent 35 U.S.C. §§ 271(a), (b) and/or (c).

95. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States their ANDA I Product and ANDA II Product before the '996 patent expires.

96. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA I Product before the '996 patent expires. On information and belief, Defendants may launch their ANDA I Product at any time.

97. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA II Product after receiving FDA final approval of ANDA No. 204206 and before the '996 patent expires.

98. Defendants maintain, on information and belief, and Plaintiffs deny that the '996 patent is invalid or unenforceable and that Defendants' ANDA I Product and ANDA II Product do not or will not infringe the '996 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '996 patent by Defendants' ANDA I Product and ANDA II Product.

99. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

100. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of ANDA Product I or ANDA Product II will infringe one or more claims of the '996 patent.

COUNT V
(DECLARATORY JUDGMENT AS TO THE '190 PATENT)

101. Plaintiffs incorporate by reference paragraphs 1–100 of this Complaint as if fully set forth herein.

102. The '190 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

103. On information and belief, Defendants' ANDA I Product and ANDA II Product are prepared by a process patented in the '190 patent. On information and belief, Defendants are aware that Defendants' ANDA I Product and ANDA II Product are so made or so adapted.

104. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA I Product and ANDA II Product before the expiration of the '190 patent constitute infringement of the '190 patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (g).

105. On information and belief, Defendants have previously filed patent certifications in association with their ANDA Nos. 202461 and 204206 seeking, *inter alia*, FDA final approval to market Defendants' ANDA I Product and ANDA II Product before February 28, 2023.

106. The ANDA I Notice Letter and the ANDA II Notice Letter show Defendants' intent to market the ANDA I Product and the ANDA II Product before the '190 patent expires on May 31, 2022.

107. On information and belief, Defendants received FDA final approval to market the ANDA I Product on September 27, 2013. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA I Product before the expiration of the '190 patent will infringe the '190 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

108. On information and belief, Defendants continue to seek FDA final approval for ANDA Product II. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA II Product, if approved, will infringe the '190 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

109. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States their ANDA I Product and ANDA II Product before the '190 patent expires.

110. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA I Product before the '190 patent expires. On information and belief, Defendants may launch their ANDA I Product at any time.

111. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA II Product after receiving FDA final approval of ANDA No. 204206 and before the '190 patent expires.

112. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '190 patent by Defendants' ANDA I Product and ANDA II Product.

113. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

114. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of ANDA Product I or ANDA Product II will infringe one or more claims of '190 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the'636, '996, and '190 patents are valid and enforceable;

B. A judgment that the submission of ANDA No. 204206 by Defendants infringes one or more claims of the'636 and '996 patents under 35 U.S.C. § 271(e)(2)(A);

C. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendants' ANDA No. 204206 shall be no earlier than the expiration date of the'636 and '996 patents or any later exclusivity to which Plaintiffs are or become entitled;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 204206 no earlier than the expiration date of the'636 and '996 patents or any later exclusivity to which Plaintiffs are or become entitled;

E. A declaration that Defendants have infringed the patents-in-suit;

F. A declaration that the commercial use, sale, offer for sale, manufacture in the United States and/or importation into the United States by Defendants of the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 202461 or ANDA No. 204206 would infringe the patents-in-suit;

G. An order preliminarily and permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the

naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 202461 or ANDA No. 204206 no earlier than the expiration date of the'636, '996, and '190 patents or any later exclusivity to which Plaintiffs are or become entitled;

H. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

I. Costs and expenses in this action; and

J. Such further and other relief as this Court may deem just and proper.

Dated: June 18, 2015

Respectfully submitted,

By: *s/ John E. Flaherty*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing First Amended Complaint for Patent Infringement and supporting documents were caused to be served on June 18, 2015, by electronic mail and/or the ECF system upon all counsel of record.

By: *s/ John E. Flaherty*
John E. Flaherty